

April 2, 2001

VETERINARY SERVICES MEMORANDUM NO. 800.52

Subject: Export Certificates and Certificates of Licensing and Inspection for Animal Biological Products

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Directors, VS Regions
Area Veterinarians in Charge, VS

I. PURPOSE

This memorandum describes the procedures for handling APHIS Form 2017, Official Export Certificate for Animal Biologics Products, and APHIS Forms 2046, 2046S, 2047, and 2047S, Certificate of Licensing and Inspection. Certification is a service provided to licensees under 9 CFR 112.2(e).

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum 800.52, dated September 7, 1999.

III. PROCEDURES FOR APHIS FORM 2017, OFFICIAL EXPORT CERTIFICATE FOR ANIMAL BIOLOGICAL PRODUCTS

A. Preparation and Submission

The licensee should submit an original of the completed APHIS Form 2017, Official Export Certificate for Animal Biological Products, to:

Center for Veterinary Biologics
Inspection and Compliance
510 South 17th Street, Suite 104
Ames, IA 50010-8197

Note: More than one biological product may be listed on each form, but only one destination may be designated. Draw a diagonal line through unused space in Blocks 3-9.

B. Processing by the Center for Veterinary Biologics (CVB)

The completed APHIS Form 2017 will be compared to information on the APHIS Form(s) 2008 submitted for the serials listed on the export certificate.

1. Satisfactory submissions - If there are no discrepancies, CVB will number, date, sign, and emboss the CVB seal on the form.
2. Unsatisfactory submissions - If discrepancies are found, CVB will return the form for correction.
3. Unreleased serials - If the serials have not yet been released, CVB will hold the form until the APHIS disposition is known and process accordingly.
4. Disposition - After completion, CVB will make and retain one copy. The original will be returned to the licensee.

IV. PROCEDURES FOR APHIS FORMS 2046, 2046S, 2047, AND 2047S, CERTIFICATES OF LICENSING AND INSPECTION**A. Preparation and Submission**

English and Spanish language variations of the Certificate of Licensing and Inspection for restricted or non-restricted product are available. Using the table below, select the appropriate form to comply with requirements of the country of destination. If Spanish-language Certificates are requested, also submit an accurate, complete English translation for reference.

APHIS Form	Product License	Language
2046	Unrestricted	English
2046S	Unrestricted	Spanish
2047	Restricted	English
2047S	Restricted	English

B. Required Information

Typically, certificates will reflect the most recent change made to the establishment or product license. If original licensing information is preferred, such preference must be requested in a cover letter accompanying the certificate(s).

Using the appropriate form, provide the following information. Do not abbreviate.

1. Name and address of the manufacturer (licensee), block 1.
2. United States Veterinary Biologics Establishment License number and date of issue, blocks 2 and 3.
3. True name of product and date product license was issued, exactly as they appear on the United States Veterinary Biological Product License, blocks 4 and 7.
4. Manufacturer's trade name for the product exactly as it appears on the label approved for filing by APHIS. Draw a diagonal line through block 5 if the certificate is to be issued without a trade name.
5. If the country of destination requires dose composition information or copies of labels or circulars, append these to the certificate.
6. For Forms 2046 and 2046S, more than one product may be listed. Draw a diagonal line through unused space in blocks 4-7.

Attach a cover letter describing the completed certificate(s) and submit the request to CVB-IC at the address indicated in section III. A. of this document. Include any requests for special processing (e.g., stamping or signing over fan-folded corners, return by special courier, etc.).

Note: If appended information causes the certificate to be more than 1 page in length, number each page and state the total number of pages (e.g., page 1 of 4). Place sufficient identifying information (e.g., establishment number, product code) on each page so that each can be identified independently should they become separated.

C. Processing by the CVB

CVB will assign a certificate number, sign, date, and emboss the CVB seal on certificates verified by information in CVB files. CVB will emboss its seal and place the certificate number on each page of a multi-page certificate, but only those pages bearing a signature line will be signed. If variations on this format are needed to comply with the requirements of the country of destination, request the changes in a cover letter accompanying the certificates.

CVB will retain a copy of the signed certificate for its files. The original will be returned to the requester.

/s/ Chester A. Gipson for

Alfonso Torres
Deputy Administrator
Veterinary Services